# THE JANSSON FIRM

3616 Far West BLVD #117-314 Austin, TX 78731

USA Phone: 512 372 8440

Fax: 512 597 0639

Send to/An/Pour: Examiner Brittany Martinez			From/Von/De: Pehr Jansson		
Attention/Zu Händen von/A l'attention de:			Date/Datum/Date: March 29, 2010		
Fax number/Fax nr./N° de fax: 571 270 4586			Phone number/Tele fon/N° de tél.: 512 372 8440		
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Urgent/ Dringend/ Urgent	Reply ASAP/ Rückantwort/ Réponse urgente	Please comment/ Erledigung/ Commentaires attendus		Please review/ Überprüfung/ A vérifier	For your information/ Kenntnisnahme/ Copie pour information

Total pages, including cover sheet: Anzahi der übermittelten Seiten inkl. Deckblatt Nombre de pages (Page de garde incluse)

# Comments/Anmerkungen/Commentaires

Dear Examiner Martinez

Again thank you for your time on March 8, 2010. My travel made it very difficult to coordinate getting the declaration drafted, reviewed, and signed sooner. Please do not take this delay to mean that we do not consider the case important.

I have attached for your review draft copies of the response and the declaration. While Dr. Sanchez has executed the declaration, please consider it as an informal draft. We can cenainly amend it if there is something in the form or substance that you would require.

Please feel free to call to discuss (512 372 8440).

With best regards.

Pehr Jansson Rcg. No. 35,759

PATENT

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/536,853

Applicant : AZNAR, Pascal

Filing Date : 2005-05-27

Confirmation No.: 4377

Art Unit : 4116

Examiner : MARTINEZ, Brittany M

Docket No. : 103.001

Customer No. : 41754

Mail Stop Amendments Commissioner for Patents

P.O.Box 1450

Alexandria, VA, 22313-1450

# AMENDMENT AND RESPONSE UNDER 37 CFR 1.115

Dear Sir:

In response to the Office Action of December 17, 2009 with a period for response extended to expire after April 17, 2009, please amend the above-identified application as follows.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 3 of this paper.

Each section begins on a separate sheet in accordance with the revised format practice.

Application #10/536,853 Amendment Dated: March 29, 2010

#### Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

## Listing of Claims:

- (Currently Amended) A <u>flash chromatography</u> column for flash ehrematography comprising spherical and porous silica gel having particle size between 3 and 45 um and pores between 30 and 300Å.
- (Currently Amended) A <u>flash chromatography</u> column for flash ehromatography with semi-spherical and porous silica gel having particle size between 3 and 45 μm and pores comprised between 30 and 300Å.
- 3. (Previously Presented) The <u>flash chromatography</u> column for flash chromatography according to claims 1 or 2 containing between 10 mg to 1 kg of spherical and porous silica gel or semi-spherical and porous silica gel.
- (Previously Presented) The <u>flash chromatography</u> column for flash chromatography according to claims 1 or 2 manufactured with tubes as well as with syringe bodies or similar forms.
- 5. (Previously Presented) The <u>flash chromatography</u> column for flash chromatography according to claim 3 and manufactured with tubes as well as with syringe bodies or similar forms.
- (Previously Presented) A <u>flash chromatography</u> column for flash ehrematography according to claims 1 or 2 adapted to purify synthetic products in quantities comprised between 10 mg to 100 g.

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#### Remarks:

In the Office Action mailed on December 17, 2010, the Examiner rejected claims 1-6.

#### Status of the Claims

In the Office Action mailed on December 17, 2010, the Examiner rejected claims 1-6. Claims 1-6 are amended herein. Claims 1-6 are now pending in the application.

#### Interview Summary

An interview was held on March 8, 2010. The examiner's Interview Summary accurately reflects the substance of the interview, and is incorporated herein by reference. Applicant gave a presentation of his inventive technology in the context of the prior art. Applicant and the Examiners discussed various different approaches to claiming the invention. The Examiners suggested an amendment of the claims as set out herein above which the Applicant agreed to. The Examiners further requested and the Applicant agreed to that Applicant would provide a declaration under 37 CFR 1.132 providing evidence of the differences in the columns used in flash chromatography and in high-performance liquid chromatography.

Applicant and Applicant's undersigned representative thank the Examiners for granting the interview and spending time discussing the prior art of record and the claimed invention. The undersigned applogizes for the delay in preparing and filing this response. The undersigned had a very heavy travel schedule over the last several weeks and was unable to devote much time to the present application.

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#### The Claims

#### 35 USC 112, second paragraph

Claims 4 and 5 stand rejected under 35 USC 112, second paragraph because it was deemed that the meaning of "similar forms" was unclear. Applicants have amended the claims to remove this language. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

## 35 USC 103

Claims 1-6 were rejected under 35 U.S.C. 102 and 35 U.S.C. 103(a) as unpatentable over a variety of references taken from the High-Performance Liquid Chromatography (HPLC) and Solid Phase Extraction (SPE) arts. The differences between the prior art of record and the claimed invention were discussed at length in the interview of March 8, 2010.

Applicants have provided a declaration under 37 CFR 1.132 by Dr. Domingo Sanchez. Dr. Sanchez, an expert in the field of chromatography, declares that there are large differences between the prior art of record, notably from the fields of HPLC and SPE and the field of flash chromatography, notably in the equipment used and the principles by which the respective separation techniques operate. Due to these differences, Dr. Sanchez concludes, a person of ordinary skill in the art would not expect success in adopting solutions from HPLC and SPE to flash chromatography.

Thus, for the reasons given above, Applicants respectfully request withdrawal of the rejection of Claims 1 through 6 and their early allowance.

The application is now deemed to be in condition for allowance and notice to that effect is solicited.

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To: Brittany Martinez Page 6 of 10 2010-03-29 16:17:32 (GMT) From: Pehr Jansson

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# CONCLUSION

It is submitted that all of the claims now in the application are allowable. Applicants respectfully request consideration of the application and claims and its early allowance. If the Examiner believes that the prosecution of the application would be facilitated by a telephonic interview, Applicants invite the Examiner to contact the undersigned at the number given below.

Applicants respectfully request that a timely Notice of Allowance be issued in this application.

Respectfully submitted.

Date: March 29, 2010 /Pehr Jansson/

Pehr Jansson

Registration No. 35,759

The Jansson Firm 3616 Far West BLVD #117-314 Austin, TX 78731 512-372-8440 512-597-0639 (Fax) pehr@thejanssonfirm.com

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PATENT

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. . 10/536,853 Applicant : AZNAR, Pascal Filing Date 2005-05-27 :

Confirmation No. :

Art Unit

: Examiner : MARTINEZ, Brittany M

4377

4116

Docket No. : 103,001 Customer No. : 41754

#### DECLARATION UNDER 37 C.F.R. SECTION 1.132

## I, Domingo Sanchez, Ph. D., declare and say:

That I am a citizen of Spain and I reside at Lilla Madviksvägen 34, 448 96 Tollered, Sweden.

That I graduated in 1978 from Chalmers University of Technology/Gothenburg University located in Göteborg, Sweden with a Ph.D degree in Organic Chemistry

That since 1984 I have been working in the field of chromatography for approximately 25 years, including development and marketing of silica-based packing materials to be used in the purification of pharmaceuticals by High Performance Liquid Chromatography, HPLC.

I am the author of approximately 50 peer-reviewed scientific papers and hold 5 patents, in the fields of Organic Chemistry and Chromatography.

#### Application #10/536,853

I have been employed by Akzo Nobel from 1984. My work at Akzo Nobel has been in the field of chromatography.

I am very knowledgeable in regard to the fields of Flash Chromatography, High Performance Liquid Chromatography (HFLC), and Solid Phase Extraction (SPE).

That I am familiar with the above-identified patent application Serial Number 10/536,853 and with the following references cited by the Examiner in the Office Action of December 17, 2010.

That the following accurately describes the differences between Flash Chromatography equipment and HPLC equipment:

- That Flash Chromatography operates at very low driving pressures; in the range of 2 - 8 bars.
- That HPLC operates at very high pressures; up to and sometimes exceeding 400 bars.
- That Flash Chromatography is typically performed using inexpensive plastic columns not designed for high pressures.
- That the packing process used to pack HPLC columns involves high pressures.
- That the high pressures used in packing and operating HPLC equipment require equipment designed for such high pressures, for example, stainless steel columns with walls approximately 1/8 " thick.
- That the high pressures encountered in HPLC manufacturing and operations would destroy

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Flash Chromatography equipment as the latter is not designed for such high pressures.

 That because of the differences between Flash Chromatography and HPLC a person of ordinary skill in the art would not expect success in adopting solutions found in HPLC to problems encountered in Flash Chromatography.

That the following accurately describes the differences between SPE and Flash Chromatography:

- SPE is a method where substances dissolved in a solvent are <u>adsorbed</u> to a powder material, usually irregular silica particles of large, -40-60μm, particle size packed in open cartridges.
- Flash Chromatography is a chromatographic method. A mixture of substances dissolved in a solvent is injected into a closed column (also known as a cartridge) containing a stationary phase, and partitioned by differences in affinity to the stationary phase.
- In SPE, after the adsorption, the desired substance is desorbed (i.e., extracted) from the adsorbing phase by a solvent other than the solvent used for the adsorption.
- In Flash Chromatography, during the elution process, i.e., the process in which the mixture flows through the column after being injected into the column, the desired substance may be

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recovered by collecting that product as the corresponding fraction exits the column with the solvent.

- The entire SPE process is performed under aspiration (i.e., under a vacuum).
- Flash columns are run at over pressure of 2 8 bar created by a pump.
- Because these differences Flash Chromatography and SPE a person of ordinary skill in the art would not expect success in adopting solutions found in SPE to problems encountered in Flash Chromatography.

That the undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon;

Further declarant saith not.

Date: March, 19, 2010 Sprin

Domingo Sanchez, Ph. D.

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